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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,197	09/22/2005	Christian Lubrano	0512-1256	8658
<div>466                      7590                      12/05/2007</div> <div>YOUNG &amp; THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202</div>				
			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 12/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,197	<b>Applicant(s)</b> LUBRANO ET AL.	
	<b>Examiner</b> Snigdha Maewall	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-14 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/13/2005</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Summary***

1. Receipt of Preliminary Amendments and IDS filed on 01/13/2005 is acknowledged.

Claims 8-14 are pending in this application and claims **8-14** will be prosecuted on the merits.

This application is a 371 of PCT/FR03/02109 07/07/2003.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 8 recites the limitation "cosmetically acceptable vehicle". The phrase does not recite the specific components, in the absence of structural limitations; the structural and functional relationship cannot be deduced. Appropriate recitation of specific components is requested.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "solids". It is unclear as to which solids is the applicant referring to. Recitation of specific components is requested. Claim 14 is indefinite because it is not clear what applicant means by external attacks. Clarification is requested.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Boss (US PG pub 2003/0114724 A1).

Boss teaches a biopolymer comprising polyubiquitin and other cross linking agents. The biopolymer offers large number of formulation because the number of ubiquitin and cross-linking agents can vary both in length and ratio (abstract). The matrix formed by the composition includes capsule, tablets, films, hydrogels and may serve as drug reservoir, drug delivery system, biosensor and skin and wound sealer. The composition can include pharmaceutical carriers or excipients (see page 4, paragraph [0053]. Since the biopolymer comprising ubiquitin is suitable to be introduced to human beings and is non-toxic, biodegradable and are suitable to be used as hemostatic agents, scaffolds, prosthesis and implants to replace damaged or diseased tissue as taught in paragraph [0057] and [0058] on page 4 and 5), the composition satisfies the limitation of being cosmetic in nature.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boss ((US PG pub 2003/0114724 A1) in view of Kenward et al. (US PG pub 2003/0228612 A1).

The teachings of Boss have been discussed above. Boss does not specify ubiquitin from alfalfa plant or the use of ubiquitin in combating skin aging or protecting against external attacks. Kenward teaches ubiquitin coming from alfalfa plant. Kenward et al. discloses an invention directed to novel nucleic acid molecules that encode epidermal growth factor protein. The nucleic acid molecules, vectors and transgenic plants are useful for achieving large scale EGF (abstract). EGF is known to promote new growth of epithelial cells (e.g. skin, cornea etc.). The EGF is used in cosmetic skin care treatments.(see paragraph[ 0007] and [0008]). The invention relates to the extraction of EGF from transgenic plants for cosmetic, medicinal and nutritional practices (see paragraph [0049]). The protein may be formulated into topical application (cosmetic ).The constitutive promoters used in the invention are ubiquitin (see paragraph [0088] ).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to utilize plant derived ubiquitin as taught by Kenward et al. in the composition of Boss because Kenward teaches that EGF such as ubiquitin can be used in cosmetic treatments and helps in promoting epithelial cells (related to skin and cornea etc.). One skilled in the art would have been motivated to utilize alfalfa derived ubiquitin in a cosmetic composition in treating skin aging with a reasonable expectation of success based o n the combined teachings of Boss and Kenward et al.

10. Claims 8 -9 and 13- 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boss (US PG pub 2003/0114724 A1) in view of Burmer et al. (US PG pub. 2002/0098495 A1) and US 2002/0012927 A1).

The teachings of Boss have been discussed above. Boss does not specifically teach skin combating or skin protecting composition. However, Burmer et al. discloses an invention relating to the discovery of nucleic acids and proteins associated with aging, particularly skin aging (title and abstract). The identification of the aging – associated nucleic acids and proteins have diagnostic uses in detecting the aging status of a cell population as well as application for gene therapy and the delaying of the aging processes (abstract). The disclosure teaches a method for inhibiting cell senescence, said method comprising the step of introducing into a cell a molecule, wherein underexpression of said senescence associated molecule is indicative of senescence. The senescence associated molecule is introduced in to the cell and the molecules are depicted in table 1 (see paragraph [0011] on page 2. Table 1 includes ubiquitin as one of the proteins which is listed on page 20. Based o n the disclosure of the prior art, it is apparent that ubiquitin helps in combating skin aging.

Burmer et al. in US publication dated Jul. 25, 2002 teach proteins associated with aging, the invention relates to the discovery of nucleic acids and proteins associated with the aging processes such as proliferation and senescence and the diagnostic uses of the proteins and nucleic acids in gene therapy and delaying of the aging processes

(abstract). Ubiquitin has been disclosed in Table 12 on page 23 to be associated with delaying the aging process.

Therefore, it would have been obvious to the one of ordinary skilled in the art at the time the invention was made to utilize ubiquitin in the composition as disclosed by Kenward et al. in view of Burmer et al. which discloses that ubiquitin is associated with treating skin aging. One skilled in the art would have been motivated to utilize ubiquitin with a reasonable expectation of success because ubiquitin has been taught to be effective in combating skin aging by both the references of Burmer et al.

11. Claims 8 -9 and 13- 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boss (US PG pub 2003/0114724 A1) in view of Pauly et al. (US PG PUB 2003/0138502 A1).

The teachings of Boss have been discussed above; Boss does not specifically teach protecting skin or combating aging. Pauly teaches a process of protecting human skin from environmental influences involving applying a composition on to the skin comprising active agents in an amount sufficient to increase heat shock protein formation in skin cells (abstract). Ubiquitin has been listed as one of the heat shock proteins on page 1, paragraph [0003] and Table 1. The reference also teaches cosmetic preparations and skin care preparations in paragraph [0001] and [0011]. Therefore it apparent that ubiquitin is an important component in skin aging treatment.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to prepare a cosmetic composition comprising ubiquitin in a



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cosmetically acceptable vehicle with the expectation of the composition exhibiting skin aging treatments since Pauly teaches a connection between skin treatments and ubiquitin. One skilled in the art would have been motivated to prepare a cosmetic composition comprising ubiquitin with a reasonable expectation of success based on the teachings and guidance provided by Boss and Pauly et al.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

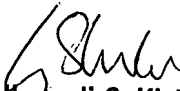
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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